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10/529,108	09/12/2005	James C. Peacock III	53233-00004 US	1761

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ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,108	PEACOCK ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03/24/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/24/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/24/2005, 12/13/2007, 8/30/2006.

DETAILED ACTION

Claim Objections

1. Claim 93 is objected to because of the following informalities: --then-- should be replaced with --than--. Appropriate correction is required.

2. Claim 98 is objected to because of the following informalities: "second" is repeated twice in line 4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 95 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 95 recites the limitations "said first lattice structure" in line 2 and "said second lattice structure" in line 6. There is insufficient antecedent basis for these limitations in the claim.

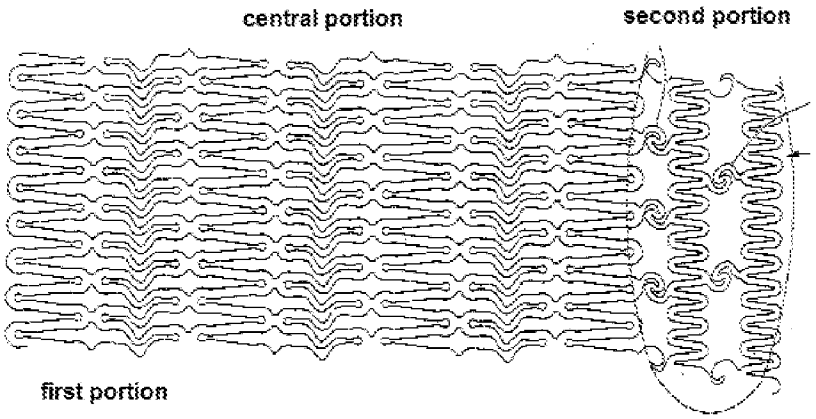
Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 83-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Von Oepen (US 6,017,365).

Regarding claims 83, 84, 85, 88-92, Von Oepen discloses a stent assembly comprising: an expandable stent having a length and having a first end portion (5), a second end portion (4') and a central portion disposed between said first and second end portions with said first end portion, said second end portion and said central portion defining a longitudinal axis along the length of said stent; said first end portion having a first lattice structure when the stent is expanded; said second end portion having a second lattice structure when the stent is expanded; and wherein said first and second lattice structures are different.



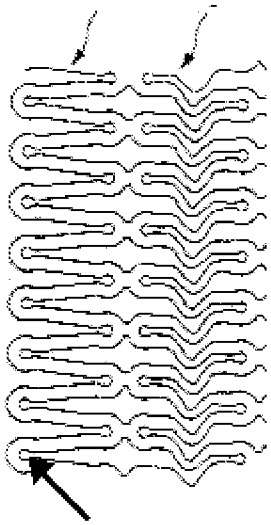
Regarding claim 84, Von Oepen discloses said first lattice structure comprises a circumferential array of M first end crowns (5); and said second lattice structure comprises a circumferential array of N second end crowns (10) (Fig. 2,3).

Regarding claim 85, Von Oepen discloses said central portion comprises a third lattice structure; and wherein said third lattice structure is substantially similar to said first lattice structure (5) (Fig. 2,3).

Regarding claim 88, Von Oepen discloses N (10) is greater than M (5) (Fig. 2,3).

Regarding claim 89, Von Oepen discloses said first lattice structure comprises a first circumferentially undulating pattern with a plurality of first strut segments wherein said circumferential array of M first end crowns (5) is formed between adjacent first strut segments with said first undulating pattern having a first amplitude; said second lattice structure comprises a second circumferentially undulating pattern with a plurality of second strut segments wherein said circumferential array of N second end crowns (10) is formed between adjacent second strut segments with said second undulating pattern having a second amplitude; and wherein said first and second amplitudes are different (Fig. 2,3).

Regarding claim 90, Von Oepen discloses said first lattice structure comprises a circumferentially undulating pattern with a plurality of strut segments wherein said circumferential array of M first end crowns (5) is formed between adjacent converging strut segments; and at least one of said first end crowns comprises a curvilinear bulb-shaped member (as indicated by the arrow in the figure below) extending longitudinally and circumferentially from respective ends of two converging strut segments (Fig. 2,3).



Regarding claim 91, Von Oepen discloses each of said first end crowns (5) comprises a curvilinear bulb-shaped member (as indicated by the arrow in the figure above) extending longitudinally and circumferentially from respective ends of two adjacent converging strut segments (Fig. 2,3).

Regarding claim 92, Von Oepen discloses in a radially expanded condition: said circumferential array of M first end crowns (5) have a first inter-crown distance between facings sides of adjacent first end crowns; said circumferential array of N second end crowns (10) have a second inter-crown distance between facings sides of adjacent second end crowns; and wherein said first and said second inter-crown distances are different (Fig. 2,3).

Regarding claims 83, 84, 86, and 88, Von Oepen discloses a stent assembly comprising: an expandable stent having a length and having a first end portion (4'), a second end portion (5) and a central portion disposed between said first and second end portions with said first end portion, said second end portion and said central portion defining a longitudinal axis along the length of said stent; said first end portion having a first lattice structure when the stent is expanded; said second end portion having a second lattice structure when the stent is expanded; and wherein said first and second lattice structures are different.

Regarding claim 84, Von Oepen discloses said first lattice structure comprises a circumferential array of M first end crowns (10); and said second lattice structure comprises a circumferential array of N second end crowns (5) (Fig. 2,3).

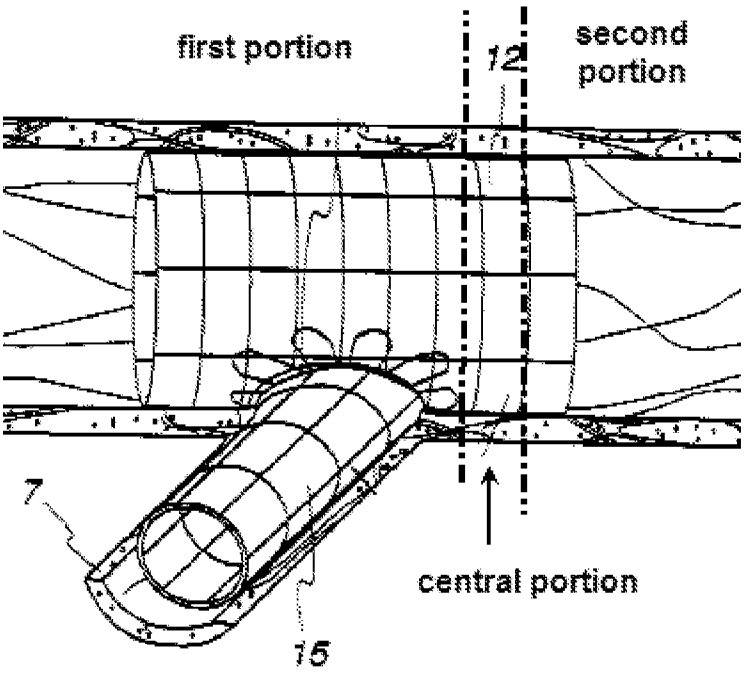
Regarding claim 86, Von Oepen discloses the central portion comprises a third lattice structure; and wherein said third lattice structure is substantially similar to said second lattice structure (Fig. 2,3).

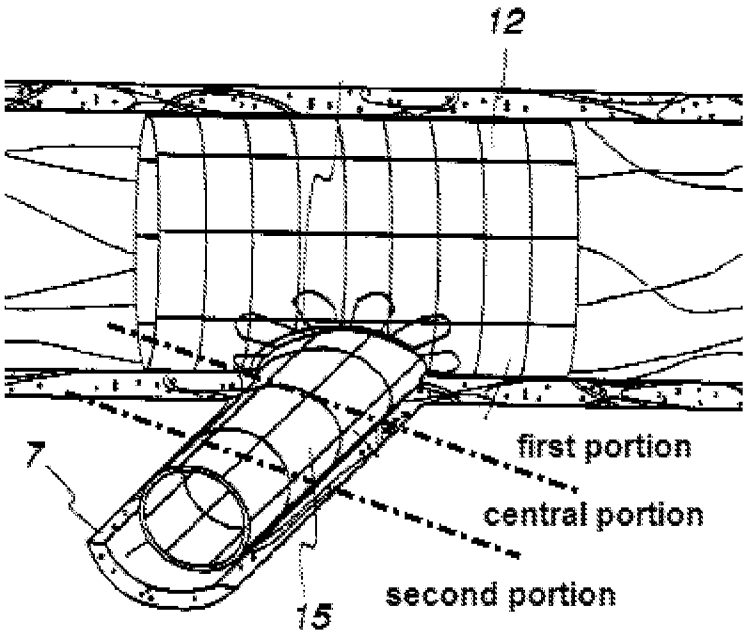
Regarding claim 87, Von Oepen discloses M (10) is greater than N (5) (Fig. 2,3).

3. Claims 94, 95, and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Vardi et al. (US 2002/0042650).

Regarding claim 94, Vardi et al. disclose a stent assembly for implanting at least two stents (12,15) at a location within a lumen, comprising: first (54) and second (48) delivery systems each having a proximal end and a distal end that is adapted to be positioned at a location within a lumen; first and second stents each with a first end portion, a second end portion and a central portion (see figures provided below) disposed between said first and second end portions; said first end portion, said second end portion and said central portion defining a longitudinal axis along the length of each of said stents; each of said first end portions having a lattice structure that is different than a lattice structure along the corresponding central portion and also different than a lattice structure along the corresponding second end portion; said first stent (15) is mounted on the distal end of said first delivery system (54) with said first end portion located proximally of said second end portion; said second stent (12) is mounted on the distal end of said second delivery system (48) with said first end portion located distally of said second end portion; each of said first and second stents having a radially collapsed condition for delivery to said location; wherein at said location each of the said first and second stents are adjustable from the respective radially collapsed condition to a radially expanded condition.

Regarding claim 95, Vardi et al. disclose the first lattice structure comprises a first circumferentially undulating pattern with a plurality of first strut segments wherein said circumferential array of M first end crowns is formed between adjacent first strut segments with said first undulating pattern having a first amplitude; said second lattice structure comprises a second circumferentially undulating pattern with a plurality of second strut segments wherein said circumferential array of N second end crowns is formed between adjacent second strut segments with said second undulating pattern having a second amplitude; and wherein said first and second amplitudes are different.





Regarding claim 97, Vardi et al. disclose the radially expanded condition at said location the respective first ends of the first and second stents confront one another such that the respective confronting first ends overlap one another at an overlap region (Fig. 6c-6e).

4. Claim 105 is rejected under 35 U.S.C. 102(b) as being anticipated by Limon (US 6,273,910).

Regarding claim 105, Limon discloses a stent (10) having a length and having a first end portion (14), a second end portion (16) and a central portion (15) disposed between said first and second end portions with said first end portion, said second end portion and said central portion defining a longitudinal axis along the length of said stent; said stent made of a non-superelastic, non-shape memory metal alloy (col. 10, ln. 52); said stent having a radially collapsed condition with a collapsed diameter, for delivery to a location within a lumen, said collapsed diameter being plastically deformed from an initial condition having an

initial diameter; wherein at said location said stent is expanded by the application of force from said collapsed diameter to a radially expanded diameter that is greater than the collapsed diameter; and wherein said initial diameter has a value that is closer to said expanded diameter than to said collapsed diameter (col. 8, ln. 54 - col. 9, ln. 5).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Von Oepen (US 6,017,365) in view of Vallana et al. (US 2003/0028242).

Regarding claim 93, Von Oepen discloses said stent assembly is adapted to be delivered to a location in a lumen; said first end portion (4') adapted to be the proximal end portion of said stent assembly; said second end portion adapted (5) to be the distal portion of said stent assembly; said first end portion having a denser lattice structure than said second end portion. Von Oepen fails to disclose said first end portion is adapted to deliver a therapeutic dose of the bioactive agent. Vallana et al. disclose providing a stent with therapeutic agents to treat the vessel lumen to reduce inflammation (paragraphs 52-54). Therefore, it would have been obvious to one of ordinary skill in the art to couple the stent of Von Oepen with a bioactive agent in order to locally deliver therapeutic drugs, such as anti-inflammatory drugs, to the lumen. It follows that the first portion would then

be adapted to delivery the therapeutic dose over a denser pattern because the lattice of the first portion is denser than the lattice structure of the second portion.

7. Claims 96 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. (US 2002/0042650) in view of Davidson et al. (US 7,220,275).

Regarding claim 96, Vardi et al. disclose the claimed invention except for a bioactive agent in association with said first end portion and said second end portion and said central portion of said stent. Davidson et al. disclose a bifurcated stent having a bioactive agent in association with the main and branch stents (col. 20, ln. 40-55). Davidson discloses having high concentration of a anti-restenosis agent at the open ends of the stents (second portions of the main and branch stents) and lower concentration at the bifurcated section (first portion). It would have been obvious to one of ordinary skill in the art to provide a bioactive agent having a higher elution profile in the second portion to prevent restenosis.

Regarding claim 98, Vardi et al. disclose the claimed invention except for a bioactive agent in association with said first and said second stent. Davidson et al. disclose a bifurcated stent having a bioactive agent in association with the main and branch stents (col. 20, ln. 40-55) . Davidson discloses having high concentration of an anti-restenosis agent at the open ends of the stents (second portions of the main and branch stents) and lower concentration at the bifurcated section (first portion). Therefore, it would have been obvious to one of ordinary skill in the art to provide a bioactive coating having a lower elution profile at the overlapped region of the first and second stents in order to prevent restenosis as suggested by Davidson et al.

Vardi et al. modified by Davidson et al. disclose the claimed invention except for the elution profile at the overlap region substantially less than double

an elution profile along the respective second and central portions of the first and second stents. Davidson et al. discloses providing higher concentration of drugs and/or at the ends of the stents but does not disclose that the concentration at the overlap being less than double the concentration at the other portions. It would have been within the routine skill of one of ordinary skill in the art to determine through routine experimentation and based on the teachings of Davidson, that the appropriate amount of drug concentration at the overlap should be substantially less than double the other portions of the stent in order to properly treat the lesion and the surrounding tissue.

8. Claims 99-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limon (US 6,273,910) in view of Vallana et al. (US 2003/0028242).

Regarding claim 99, Limon discloses a stent assembly comprising: a stent having a length and having a first end portion (16), a second end portion (14) and a central portion (12) disposed between said first and second end portions with said first end portion, said second end portion and said central portion defining a longitudinal axis along the length of said stent (Fig. 4); Limon fails to disclose a bioactive agent coupled to said stent. Vallana et al. disclose a bioactive agent coupled to the stent and a first elution profile along that portion of the longitudinal axis defined by the first end portion; a second elution profile along that portion of the longitudinal axis defined by the second end portion; a third elution profile along that portion of the longitudinal axis defined by the central portion; and wherein the first elution profile is greater than the third elution profile thereby the stent exhibits a gradient of elution profile with respect to the bioactive agent along the length of the stent (Fig. 10B). Therefore, it would have

been obvious to one of ordinary skill in the art at the time of the invention to provide a stent with a bioactive agent so the stent exhibits a gradient elution profile along the length of the stent as taught by Vallana et al. because certain regions of the vessel require more drug treatment than others (paragraph 37).

Regarding claims 100 and 101, Limon discloses the first end portion (16) having a circumferential array of first end crowns; and one or more enlargements (26) on said first end crowns (Fig. 4). Limon discloses enlargements are partially circular bulb-shaped enlargements (26) extending from said first end crowns in a longitudinal direction away from said central portion (Fig. 4).

Regarding claim 103, Limon discloses the first end portion (16) has a first scaffolding pattern; said second end portion (14) has a second scaffolding pattern; said central portion (12) has a third scaffolding pattern; and wherein said first scaffolding pattern is denser than said third scaffolding pattern (Fig. 4).

Regarding claim 104, Limon discloses the first scaffolding pattern (16) comprises a first series of undulations having a first frequency and oriented circumferentially about said stent assembly; said second scaffolding pattern (14) comprises a second series of undulations having a second frequency and oriented circumferentially about said stent assembly; said third scaffolding (12) pattern comprises a third series of undulations having a third frequency and oriented circumferentially about said stent assembly; and wherein said first frequency is greater than said third frequency (Fig. 4).

Regarding claims 99, 100, and 102, Limon discloses a stent assembly comprising: a stent having a length and having a first end portion (14), a second end portion (16) and a central portion (12) disposed between said first and second end portions with said first end portion, said second end portion and said

central portion defining a longitudinal axis along the length of said stent (Fig. 4); Limon fails to disclose a bioactive agent coupled to said stent. Vallana et al. disclose a bioactive agent coupled to the stent and a first elution profile along that portion of the longitudinal axis defined by the first end portion; a second elution profile along that portion of the longitudinal axis defined by the second end portion; a third elution profile along that portion of the longitudinal axis defined by the central portion; and wherein the first elution profile is greater than the third elution profile thereby the stent exhibits a gradient of elution profile with respect to the bioactive agent along the length of the stent (Fig. 10B). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a stent with a bioactive agent so the stent exhibits a gradient elution profile along the length of the stent as taught by Vallana et al. because certain regions of the vessel require more drug treatment than others (paragraph 37). Limon discloses the first end portion (14) having a circumferential array of first end crowns; and one or more enlargements (26) on said first end crowns (Fig. 5). Limon discloses the enlargements are partially circular bulb-shaped enlargements (26) extending from said first end crowns (14) in a longitudinal direction toward said central portion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
6/19/08

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731